

Remarks

Upon entry of the foregoing amendment, claims 150-170 are pending in the application, with claims 150, 160, and 170 being the independent claims. Claims 150, 160, and 170 have been amended herein merely for clarification. The foregoing amendments introduce no new matter, and their entry is respectfully requested.

Based on the following remarks, applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103

Claims 150-153, 155-163, and 165-170 were rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,957,949 ("the '949 patent"). Claims 154 and 164 were rejected under 35 U.S.C. § 103(a) as obvious over the '949 patent in view of U.S. Patent No. 5,104,404 ("the '404 patent"). Applicants respectfully traverse these rejections.

Pointing only to FIGS. 2-4, the Office Action states that the '949 patent discloses: a valve support having an axial length sufficient to extend from a position of a native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into an ascending aorta, as recited in claim 150; a valve support configured to extend, when implanted into a patient, from a native annulus at the proximal portion to an ascending aorta at the distal portion, past a location of the patient's coronary ostia, as recited in claim 160; or a valve support sized and shaped to extend from a position of the native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into an ascending aorta when the valve support is implanted in a

patient and the replacement valve is positioned in a native aortic valve annulus, as recited in claim 170. Office Action, pp. 2-4. Applicants respectfully disagree that these features are taught or suggested by the '949 patent, and submit that the Office Action fails to establish a *prima facie* case of anticipation or obviousness as to claims 150, 160, and 170.

Anticipation of a claim is established only when a single prior art reference discloses, expressly or under principles of inherency, each and every element of a claimed invention. *Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131. As to obviousness,

the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined.

Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17 (1966). The Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *In re Piasecki*, 745 F.2d 1468, 1471-73, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984). "Rejections on obviousness cannot be sustained by merely conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006).

FIG. 2 of the '949 patent shows a valve stent 20 implanted at the location of a native mitral valve. '949 patent, col. 5, ll. 41-42. Stent 26 biases the proximal and distal

ends of valve stent 20 into conforming and sealingly fixed engagement with the tissue of mitral valve 14. '949 patent, col. 5, ll. 48-52. In other words, as seen in FIG. 2, valve stent 20 conforms to the tissue immediately around the location of the natural mitral valve. Valve stent 20 is not shown extending into the ascending aorta. '949 patent, FIG. 2. Indeed, as would be apparent to one skilled in the art, a prosthetic valve intended to anchor itself on the tissue immediately surrounding the native annulus of a mitral valve would not have sufficient length to extend from a native annulus into the ascending aorta. The '949 patent provides no disclosure suggesting that valve stent 20 can be expanded to a greater length, or used to replace an aortic valve. Because the Office Action simply points generally to FIGS. 2-4, which do not show a valve support configured to or having sufficient length, size, or shape to extend from a native annulus into an ascending aorta, it is unclear how the Examiner arrived at the legal conclusion that the '949 patent anticipates or renders obvious claims 150, 160, and 170. Therefore, the Office Action fails to establish a *prima facie* case of anticipation or obviousness as to claims 150, 160, and 170.

After stating that all limitations of claims 150, 160, and 170 are disclosed by the '949 patent, the Office Action broadly states that "many of the claims contain functional and intended use language." Office Action, p. 5. The Office Action further states that "[i]n order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant presence of the functional language. *Id.*, citing *In re Fuller*, 1929 C.D. 172. No further details are provided. The Office Action does not specifically point to any functional or intended use language in the claims, much less explain why any such language is not supported by a recitation of

sufficient structure in the subject claim. In fact, the Office Action does not even positively state that any claim recitation was not given patentable weight by the Examiner. The broad, unapplied statement that "many claims contain functional and intended use language" does not cure the Office Action's failure to establish a *prima facie* case of anticipation or obviousness as to claims 150, 160, and 170.

With regards to functional and intended use language, applicants generally remind the Examiner that, as detailed in MPEP § 2173.05(g), "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." *See also* MPEP § 2114. If the theory of inherency is relied upon to establish that the cited prior art is capable of performing the function recited in the subject claim, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (The Board reversed the examiner's rejection because the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

The '404 patent also fails to cure the deficiencies of the '949 patent. The '404 patent is directed to intravascular stents applied within peripheral or coronary arteries. '404 patent, col. 1, ll. 8-14. The '404 patent fails to disclose at least: a valve support having an axial length sufficient to extend from a position of a native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into an ascending aorta, as recited in claim 150; a valve support configured to extend, when

implanted into a patient, from a native annulus at the proximal portion to an ascending aorta at the distal portion, past a location of the patient's coronary ostia, as recited in claim 160; or a valve support sized and shaped to extend from a position of the native annulus, past the replacement valve, the commissure points, and the patient's coronary ostia, and into an ascending aorta when the valve support is implanted in a patient and the replacement valve is positioned in a native aortic valve annulus, as recited in claim 170.

Claims 151-159 depend from and add limitations to claim 150, and are therefore patentable for at least the same reasons as claim 150. Claims 161-169 depend from and add limitations to claim 160, and are therefore patentable for at least the same reasons as claim 160.

Applicants thus respectfully request that the examiner reconsider and withdraw the rejections of claims 150-170.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Reply to Office Action of November 10, 2009

Seguin *et al.*
Appl. No. 10/772,101

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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